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By ECF

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The Honorable Sanket J. Bulsara, U.S.M.J.
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: Biofer S.p.A. v. Vifor (International) AG., No. 1:22-cv-02180-AMD-SJB

Dear Judge Bulsara:

Pursuant to the Court's Order (D.I. 138), Vifor provides the Court with an update on the status of settlement negotiations and pending motions to compel.

As of May 14, 2024, the parties have been unable to reach a settlement. Vifor can provide additional details during the May 30th status conference. Further, as explained herein, Vifor believes Biofer's pending motions to compel, which entirely relate to infringement, should be denied as moot in light of the Court's March 29, 2024 Claim Construction Order. Vifor believes its three pending motions to compel, which are directed to the validity of the '320 patent, remain relevant.

Under the Court's Claim Construction Order (D.I. 139), Vifor does not, for several reasons, infringe the claims of the '320 patent. Consequently, Vifor requested Biofer's position on filing a stipulation of non-infringement. Biofer, however, continues to believe it can maintain an infringement action. On May 10th, Biofer confirmed in a letter that it intends to continue pursuing its infringement allegations and indicated that it will provide updated infringement discovery responses in view of the Court's Claim Construction Order. Rather than concede, Biofer suggested the parties expend additional resources by having Vifor file a motion for summary judgment of non-infringement. Biofer additionally proposed that the parties agree to stay all remaining case deadlines until the briefing on Vifor's potential motion for summary judgment of non-infringement are complete. By suggesting summary judgment, Biofer has effectively indicated that it no longer needs additional fact discovery from Vifor on the issue of infringement. Vifor is considering Biofer's proposal and will address it with Biofer prior to the May 30th status conference, and Vifor expects to provide an update to the Court at that time.



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In light of the Court’s Claim Construction Order, Vifor also provides the Court with an update on the pending motions to compel and corresponding responses listed below:

Biofer

- 12.01.23 – D.I. 106; D.I. 112
- 02.23.24 – D.I. 121; D.I. 130
- 03.05.24 – D.I. 127; D.I. 135

Vifor

- 11.27.23 – D.I. 101; D.I. 109
- 12.08.23 – D.I. 114; D.I. 115
- 01.18.24 – D.I. 119; D.I. 120

Biofer’s pending motions to compel relate solely to issues of infringement and should be considered moot given the Court’s Claim Construction Order construing the term “pH between 7.0 and 9.0” as “pH is maintained in the interval separating 7.0 and 9.0.” (D.I. 139, 9–15.) As presented in Vifor’s opposition to Biofer’s December 1, 2023 Motion to Compel, Vifor’s DMF does not permit oxidation at a pH between 7.0 and 9.0, let alone “maintaining” a pH in this interval during the duration of oxidation. (D.I. 112, 1.) Further, Vifor’s oxidation process, as disclosed in the DMF and as evidenced by the plethora of batch records produced to Biofer and additional documents describing Vifor’s automated oxidation process, does not meet the oxidation at a “pH [] maintained in the interval separating 7.0 and 9.0” limitation. (D.I. 139, 10 *see also* D.I. 130, Ex. 1, 9–15.) Additionally, Vifor’s oxidation process does not add sodium hypochlorite “slowly” as required by the claims and as described in the ’320 patent and Marchi Declaration, and does not utilize “hypochlorite being added in a 1:1 molar ratio with respect to the aldehyde end group of the sugar. . .” as construed by the Court. (D.I. 139, 16–19.)

Because Vifor’s oxidation process does not meet the claim limitations of the ’320 patent, Biofer cannot meet its burden of proof with respect to independent claim 1 of the ’320 patent, and accordingly it cannot meet its burden of proof with respect to any of the asserted dependent claims. Therefore, and consistent with Biofer’s suggestion that the issue of infringement is ripe for summary judgment, Biofer’s pending motions to compel, all concerning infringement, are moot.

Independent of the Court’s construction, Biofer’s December 1, 2023 Motion to Compel should be considered moot because Vifor, in January 2024, produced all the pH measurement data requested by Biofer and agreed to provide 30(b)(6) testimony on the topic Biofer requests, which it now appears Biofer does not need. At the same time, Vifor also identified to Biofer the software used with its reaction vessels. Because the requested data was produced, Biofer’s December 1, 2023 Motion to Compel is moot.

The portion of Biofer’s February 23, 2024 Motion to Compel regarding pH measurements for the storage of the oxidized maltodextrin (after oxidation) prior to iron complexation and requesting a sworn declaration from an individual at Vifor regarding pH measurements during and after oxidation should also be considered moot. (D.I. 121, 2–4.) Vifor agreed to provide a



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corporate witness on Topic 6, which concerns the actual measurements of pH during the oxidation step.¹ Thus even if Biofer could maintain its infringement arguments, Biofer's request for additional pH data and sworn declaration is not needed.

Sincerely,

/s/ Sanya Sukduang

Sanya Sukduang

¹ Vifor agreed to postpone the scheduled personal and Rule 30(b)(6) deposition addressing these issues, including Biofer Rule 30(b)(6) Topic 6, to accommodate Biofer's counsel.